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THE NUTS AND BOLTS OF ISO 9000 CERTIFICATION

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The ISO 9000 standards are a set of five guidelines describing minimum requirements for an organization's total quality management system (TQM). It is a comprehensive description of the necessary components in an organization's quality management and assurance structure. The focus is on the customer. The standards recognize that specifications alone do not guarantee that customer requirements are consistently met, particularly if there are deficiencies in the specification, or weaknesses in the system that designs, manufactures, inspects and tests that product or service. ISO 9000 is made up of five parts:

ISO 9000 "Quality Management and Quality Assurance Standards "Guidelines for Selection and Use."

ISO 9000, is a guide to the proper selection and use of related standards, ISO 9001, ISO 9002, and ISO 9003 for an organization in contractual situations between a supplier and its customer.

ISO 9001 "Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing."

This is the most encompassing of all five standards. It addresses all of the operations that affect the quality, or "fitness for use" of a good or service. The standard is applicable to design, manufacture of the product, as well as, in-use servicing.

ISO 9001 specifically addresses:

- Management Responsibility
- Quality System
- Contract Review
- Document Control
- Inspection & Test Status Traceability
- Corrective Action
- Quality Records
- Internal Audits
- Purchasing Supplied Product

- Training
- Statistical Techniques
- Design Control
- After-Sales Servicing
- Purchasing
- Product Identification
- Inspection of Measuring
and Test Equipment
- Control of Non-conforming
Materials
- Handling Storage
- Packaging and Delivery

ISO 9001 can be applied to manufacturing and processing companies, as well as construction, architecture, and consulting firms.

ISO 9002 "Quality Systems - Model for Quality Assurance in Production and Installation."

The purpose of ISO 9002 is to direct process and manufacturing companies that provide products and services to the customer specifications in contractual situations. Consequently, it differs from ISO 9001 in that it does not cover the design function in its model of an organization's quality assurance system. Compliance assures that a company has the capability to supply acceptable products and services and is able to document and control all mechanisms from manufacture to installation.

It differs from ISO 9001 in that it does not require demonstration of design control and after-sales service. These are beyond its scope.

ISO 9003 "Quality Systems - Model for Quality Assurance in Final Inspection and Test."

This standard is the least comprehensive of all of the series. Under ISO 9003, the organization must assure, in contractual situations, that it is capable of detecting, documenting, and controlling non-conforming material in the final inspection and test of a product or service. Companies that use this standard generally have

"The Nuts and Bolts of ISO 9000 Certification"

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ABSTRACT

The dreaded 1992 deadline is approaching and with less than nine months left, many companies have not yet received ISO 9000 series certification. The key to swift certification is information. The questions most asked are: What are the ISO 9000 series standards and what do I need to do to be certified? Who can be certified? What are the drawbacks of the ISO 9000 series standards? And more importantly, what is in it for me?

KEY WORDS

ISO (International Standards Organization)
ISO 9000 Series Standards
Total Quality Management
European Economic Community

INTRODUCTION

By the close of 1992, the European Economic Community (EC), made up of 12 countries, will have the largest single consumer market in the world, with a projected worth of over three trillion dollars. The EC is working to promote free trade of goods and services across international borders. Before this could be effectively realized, one internationally-accepted system governing contracts needed to be developed.

In an effort to tear down international trade barriers between national borders, minimum requirements in one international quality standard is needed.

WHAT IS ISO?

ISO is the acronym for the International Standards Organization. It is a standards-making organization consisting of members from 90 countries, including the United States. The mission of ISO is to "promote the development of standardization and related world activities with a view to facilitating international exchange of goods and services and to developing cooperation in the sphere of intellectual, scientific, technological and economic activity,"¹ through published international standards. The American National Standards Institute is the U.S. emissary to ISO.

WHAT ARE THE ISO 9000 SERIES STANDARDS?

The standard for quality assurance management is the ISO 9000 series standard. It evolved from the 1979 British Standard BS 5750, was revised in 1987 and incorporated into the 1987 version of the ISO 9000 series (as well as Europe's EN 29000 standard series) standards. Numerous standards bodies have also adopted the contents of these standards to effectively bind the world together under one universal ideal. These standards are not product specifications, but are instead generic quality management system models that supplement specifications. They are a "set of international standards designed to be used for establishing and maintaining quality management and systems for internal company use or to satisfy outside contracts."²

a small range of activities occurring there.

It does not cover internal quality audits, purchasing, purchaser supplied product, contract review, corrective action and process control, as required by ISO 9002.

ISO 9004 "Quality Management and Quality Systems Elements - Guidelines."

ISO 9004 identifies the necessary components of an internal quality assurance program. "This standard describes a basic set of elements by which quality management systems can be developed and implemented. The selection of appropriate elements contained in the International Standard, and the extent to which these elements are adopted and applied by a company, depends upon the factors such as the market being served, nation of the product, production processes, and consumer needs."³

ISO 9004 includes the following topics:

- Quality in marketing, production, specification, and design
- Product safety and liability
- Control in production
- Product verification
- Personnel
- Poor Quality Costs

It is important to emphasize that there are other national standard equivalents to the ISO 9000 Standard that are conceptually the same. The American Society for Quality Control (ASQC) has an equivalent called the ASQC Q90 Series.

WHAT KINDS OF COMPANIES SHOULD BE CERTIFIED?

The beauty of ISO 9000 is its generic nature. This allows diverse organizations large and small, service and manufacturing, to use them as a model, and then achieve certification. If an organization plans to:

- Seek government contracts
- Sell to the European Community (EC)
- Increase the quality of its goods and services
- Initiate a quality assurance program
- Serve customers who are themselves already ISO 9000 certified suppliers

ISO certification should be a company-wide priority. Compliance keeps a company economically competitive. Only companies whose upper management is committed to certification and the contents of the standard need apply. Half-hearted efforts with no long-term commitment are a waste of time.

HOW DO I BECOME CERTIFIED?

- Get senior management's complete commitment and support. Leadership for the demanding task must originate from the top level of the organization. This is the essential first step.
- Obtain all of the information possible on the ISO requirements from standard bodies, seminars, and others who have already gone through the registration process. Information is the key to eventual success.
- Define the scope, and identify which standard the organization (or divisions thereof) will prepare to meet.
- Develop and implement the plan of action and the estimated duration of each stage of preparation.
- Assemble a Steering Committee and appoint a Committee Leader to guide the process implementation. Representation of the senior management should also be present in the Steering Committee.

- Select an ISO registrar to register the organization, (or divisions thereof) and make an application to them for registration.
- Discuss with the registrar whether the chosen ISO standard and scope are appropriate for the activities of the area to be registered.
- Discuss with the registrar whether the chosen ISO standard and scope are appropriate for the activities of the area to be registered.
- Eradicate fear by training employees on what to expect, and what is expected from them throughout the preparation and registration processes.
- Inform the organization system using the applicable standard as a guide. Outside consultants or the organization's quality assurance personnel can lead this assessment.
- Record and update the elements of the existing quality system in the organization's quality manual. This includes defining or redefining the organization's policy, objectives, personnel responsibilities, and duties, and internal verification of requirements.
- Assemble all other documentation of the quality system activities as described by the applicable standard.
- Implement an audit function to assess compliance and conformance.
- Send a copy of the quality manual to the registrar for inspection.
- Be audited by the registrar for registration.

- Act on corrective action items uncovered by the registrar's audit team. When corrected to the auditors satisfaction, receive official certification documentation.

WHAT ARE SOME OF THE DRAWBACKS OF ISO 9000 SERIES STANDARDS?

Although ISO 9000 is technically sound, and takes a logical common sense approach to quality assurance, it does have some drawbacks. Some of these are listed below:

- It provides no mechanisms, or mandates for continuous improvement of an organization's product or service.
- The standards only assure that a company is doing what it says it is doing. It does not assure that what it is doing is "correct."
- Some words used in the standards are open to different interpretations. This makes preparation for certification more difficult. Consequently, there is some risk that two ISO certified auditors may not come to the same conclusion about an organization's quality system.
- Preparation for certification and registration are costly. It can require additional supplies, and many man-hours to affect changes in the quality system. Registration can cost thousands of dollars.
- It takes a great deal of time to register. 18 to 24 months for preparation is not an unusual time period.
- Long-term commitment is required by all employees, especially upper management, to maintain registration.

WHAT ARE THE BENEFITS OF ISO CERTIFICATION?

The benefits of ISO certification include:

ECONOMIC

First and foremost, the most important benefit of ISO certification is an increased economic advantage. Implementation of a quality system removes deterrents to productivity, such as scrap and rework. Achievement of "fitness of use" and meeting (or exceeding) customer needs and expectations is the aim of these guidelines. An effective quality system identifies and removes the root cause of potential problems and errors, especially those affecting the quality of a company's products or services. Mistakes cost money. The purpose of ISO 9000 is to eradicate mistakes. Due to decreased manufacture errors, less money is spent on the cost of product re-delivery, credit memos and warranty collections.

ISO 9000 provides an atmosphere that is conducive not only to meeting customer needs, but to the improvement of quality services.

PUBLIC RELATIONS

ISO certification is also a great marketing tool. An organization certified for ISO 9000 is internationally recognized to be concerned about the level of quality in its products and services on a company-wide basis. It assures the customer that the organization has established an extensive structure that promotes production of good products and services that meet his/her needs.

It is reasonable to state that if two organizations competing for one contract, one with certification and the other without (and all else being equal), the one with proof of certification would be the odds-on favorite for acceptance.

BETTER CUSTOMER/CLIENT RELATIONS

ISO 9000 supports an organization's reduction of suppliers. It is likely that with the reduction of suppliers, the alliance between the two will be enhanced. Both will have a stake in the improvement of the other.

QUALITY FOUNDATION

The ISO 9000 standards are basic, minimal requirements for an efficient quality system that emphasizes prevention, over the detection of errors. It is not a radical idea. Instead, it is a common sense approach that should be the norm for all companies in industrialized countries. The ISO 9000 standards are not specific; it provides only a "model" foundation for a quality system. Organizations can further tailor their quality system to suit their individual operations and needs. The standard is a basis for the initiation of a continuous improvement program.

REDUCTION OF SUPPLIER AUDITS

Supplier certification, particularly by European companies, will be minimized. The ISO 9000 guideline and its requirements correspond with those demanded by contracts. Standards for acceptance set forth in the standards are the same as those customarily in contracts. Following the guidelines for these standards to maintain certification, assures the customer that his/her needs will be fulfilled.

FUTURE: LESSONS LEARNED

Can you expect increased profit and market share, efficiency, better customer relationships with all of your client?

Of course! ISO is not designed to benefit only European customers. ISO 9000 can benefit companies everywhere if it is used as a stepping stone to more comprehensive quality system models.

ISO 9000 is not the end of the quality assurance quest. Hopefully, the international community will discover ways of vigorously standardizing methods for achieving "fitness for use."⁴ Globally we must continue the pursuit of quality.

¹ ANSI/ASC Z-1 Committee, "ANSI/ASC Z-1 Committee on Quality Assurance Answers the Most Frequently Asked Questions About the ISO 9000 (ANSI/ASQC Q90)."

² Underwriters Laboratories, Inc., "Questions and Answers About the UL ISO 9000 Registration Program," 1989.

³ International Standards Organization, ISO 9004: 1987 "Quality Management and Quality System Elements - Guidelines."

⁴ Juran, J.M., ed., Frank M. Gryna, assoc. ed., Juran's Quality Control Handbook, 4th Ed., McGraw-Hill, New York, 1988.